Declaration with Exhibits (37 CFR 1.132)

Submitted under a certificate of facsimile transmission accompanying an Amendment on April 17, 2007

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Received Cover Page =======>

APR-17-2007 09:24 FR CHRISTOPHER J RUDY 810 982 5336 P.01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Charles O. Townley
Serial No. 10/758,455
Filing Date 01/15/2004
Docket No. THUMB-004DIV
MODULAR BASAL THUMB JOINT IMPLANT

Attn: Group Art Unit 3738
Primary Examiner
Brian S. Pellegrino

Amendment

Commissioner for Patents, Alexandria, VA 22313-1450:

I certify that this correspondence is facsimile-transmitted to the Patent and Trademark Office (571 273 8100) on 17 APR 2007:

Christopher John Rudy (Reg. 47,261) 4/17/2007

Thank you for the 01/17/2007 office action for the present application. In reply to that action, please reconsider and further examine the application, and in light of the present correspondence withdraw the standing rejections.

CLAIMS AMENDMENTS are attached hereto.

This amendment more particularly points out and distinctly claims the invention, and is fully supported by the original and underlying specifications, including drawings. No new matter is added hereby. Claims 21-41 remain present. No extra fee is due.

Insofar species A is cited as a one-piece basal thumb joint implant, the traverse of the 35 USC 121 restriction of species is withdrawn. All present claims, which require modularity, read on the thus elected and examined species, B, C and D.

As may apply to the present claims, each of the rejections set forth in the outstanding action is respectfully traversed.

Regarding the rejection of claims 21-24, 26, 40 and 41 under 35 USC 102(b) over Townley, US 2004065, each of claims 21 and 41 requires a head of a size for mounting in and articulating with a correspondingly concavely preserve surface of trapezium bone stock, and its stem of a size for intramedullary insertion in metacarpal bone stock. Such size limitations are material claim elements and must be taken into account. See, In re Marshall, 578 F.2d 301 (198 USPQ 344, 346) (CCPA 1978). Townley '065 does not describe either of these size limitations. In fact, the device of Townley '065 is a hip implant, which is well known to be much larger than a basal thumb joint implant. Moreover, modularity to the hip implant of Townley '065 is not described, and unlike that found in some present claims, no guiarel angle or projection in Townley '065 is acute; it is perpendicular. Thus, claims 21, 23, 40 and 41 distinguish over Townley, and, by virtue of their dependence, claims 22, 24 and 26 distinguish as well.

FURTHER REMARKS conclude the present paper (pages 7-11).

Submitted herewith is a Declaration with Exhibits.

PAGE 1/19 * RCVD AT 4/17/2007 6:24:50 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/15 * DNIS:2738300 * CSID:810 982 5336 * DURATION (mm-ss):03-41

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Regarding: Charles O. Townley
Serial No. 10/758,455
Filing Date 01/15/2004
Docket No. THUMB-604DIV
For **MODULAR BASAL THUMB JOINT IMPLANT**

Declaration with Exhibits (37 CFR 1.132)

Attention: Group Art Unit 3738
Primary Examiner Brian E. Pellegrino

Commissioner for Patents, Alexandria, VA 22313-1450:

I, Christopher John Rudy, state and declare as follows:

I am the attorney of record (Reg. No. 31,873) in the present application and in parent Serial No. 09/352,472. I was attorney of record in the application that led to U.S. Pat. No. 6,096,084.

The inventive entity of the Townley '084 patent is the same as in the present application, Charles O. Townley. Both the invention of Townley '084 and the present invention were subject to assignment and have been assigned to the same owner, BioPro, Inc., with their assignments recorded in the Office on Reel 10155 Frames 892-894 and Reel 10116 Frames 869-870, respectively.

Attached hereto as Exhibits are copies of parts of declarations of record in the parent application, as follows:

Pages 1 (with postcard receipt) and 9-11 of the DECLARATION UNDER 37 CFR 1.132 TRAVERSING REJECTIONS of Patrick E. Pringle, filed on March 19, 2001.

Pages 1 (with postcard receipt), 3 and 4 of the DECLARATION OF MARK S. LESLIE, M.D., filed on May 22, 2000.

These verify among other things that hip implant art is not relevant to the art of basal thumb joint implants, and that the one-piece basal thumb joint implant of Dr. Townley was considered by Dr. Leslie to be clearly different from the Swanson titanium basal thumb joint of the Wright Medical Technology brochure, and that such is favorable for Dr. Townley's basal thumb implant.

All statements made herein of my own knowledge are true and on information and belief are believed to be true. Also, these statements were made with the knowledge that willful statements and the like so made are punishable by fine and/or imprisonment per 18 USC 1001 and such willful false statements may jeopardize the validity of this application or any patent issuing hereon.

Dated: April 17, 2007 A.D.

Christopher John Rudy

Townley, 10/758455 Decl. w/Exhibits (Exhibits)

Rec'd:
- Amendment after Third Interview
- SCDR 3/9/2001
- Supplemental Explanation from SCDR 3/9/2001
- DECLARATION UNDER 37 CFR 1.132 TRAVERSING REJECTIONS
- Form PTO-1449 w/ Cited References — S/PEP 3/9/2001

Re: 1 Townley
THUMB-393/440
09/352472.
Christopher John Rudy
PTO #31772 3/9/2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Regarding: Charles O. Townley
Patent Application No. 09/352,472
Original Filing Date 07/14/99
CPA Filing Date Aug. 17, 2000
For BASAL THUMB JOINT IMPLANT

Attention: Group Art Unit 3738
Examiner Brian E. Pellegrino
Primary Examiner Bruce E. Snow

Commissioner of Patents
Washington, D.C. 20231

DECLARATION UNDER 37 CFR 1.132 TRAVERSING REJECTIONS

I, Patrick E. Pringle, being warned that willful false statements and the like so made are punishable by fine and/or imprisonment under 18 USC 1001, and that such willful false statements may jeopardize the validity of this application or any patent resulting hereon, state and declare as follows:

I am the undersigned, and am a citizen of the United States of America, and a resident of Smiths Creek, Michigan.

I am employed at BioPro, Inc., the assignor of the entire right, title and interest in the invention of the application of reference, being the current president of the corporation. I have worked at BioPro, Inc. for twelve years. Among my duties there, I assist in designing, evaluating and/or manufacturing prosthetic implants such as for the knee, elbow, hip, shoulder, big toe, and basal thumb joints. I am one of the co-inventors of U.S. patent No. 5,766,257 for an artificial joint having natural load transfer.

I understand that under 35 USC 103(a) claims of the present patent application stand rejected as being unpatentable over the applied references (which references I have reviewed, with copies thereof attached) as follows: 1) claims 1-8 over Kummer et al., U.S. patent No. 5,910,171; 2) claims 1-10, 12-14 and 16 over the "Townley Modular Shoulder" (BioPro brochure); 3) claims 17-20 over the BioPro brochure in view of the "Swanson Titanium Basal Thumb Implant" (Wright Medical Technology brochure); 4) claims 11 and 15 over the BioPro brochure in view of Bekki et al., U.S. patent No. 5,007,932. I believe that I have a sufficient understanding of the present invention, and formal drawings from the application, which pictorially illustrate principles and preferred embodiments of the invention, follow:

Townley, 10/758455 Decl. w/Exhibits (Exhibits)

Townley, 09/352472 Pringle DECLARATION, p. 9

I would respectfully disagree with the reasoning of the Examiner, and think that shoulder or hip joint art, and finger joint art, are not particularly related to basal thumb joint art.

Taking the shoulder joint as exemplary of what I understand that the Examiner considers to be more relevant from among the enarthrodial type joints of shoulder and hip, it first should be mentioned that I was shocked, saying, "No way!" when I heard that shoulder joint art, particularly a humeral implant, was being applied to a basal thumb joint. These joints are not related sufficiently to be interchangeable. (A hip, although not itself particularly relevant to basal thumb joint implant art either, perhaps would be more analogous.) Several considerations come to mind in support of this: size, configuration, and implant situs.

The size of a shoulder implant is vastly greater than that of a basal thumb implant. I fail to see how a person of ordinary skill in the art is given directions from the applied art to reduce the size of a large implant, intended for one part of the anatomy, a large part at that, to a smaller implant, intended for a different, small, remote part of the anatomy.

The configuration or shape of a humeral implant differs, and in some ways significantly, from a basal thumb joint implant as well. In general, for instance, humeral shoulder implants have more acute angles of attachments of their heads than do basal thumb joint implants. For example, the head to stem angle of the Townley Modular Shoulder is about fifty degrees whereas that of the Swanson Basal Thumb Joint appears to be nearly perpendicular. The angle of attachment of the basal thumb joint of the present invention preferably is about from sixty-five to seventy-five degrees, say, about seventy degrees. As well, typically, the heads of humeral shoulder implants span less than a hemisphere whereas those of basal thumb joints span more a hemisphere. The stems of humeral shoulder implants are, in general, relatively massive and not fluted to any pronounced degree. In contrast, the basal thumb joint implant stems are more slight, in general, and the basal thumb joint implant stem of the present invention preferably has a tri-flanged stem, for example, being T-shaped in cross-section. Moreover, a humeral shoulder implant often has a relatively large, solitary fin on the lateral side of the stem by the head for stabilization whereas no such solitary fin is found in basal thumb joint implants.

The situs of the implant differs significantly between the shoulder and the basal thumb. The humeral component of a shoulder implant has a stem designed for insertion into the upper reaches of a resected humerus, and has a head designed for mating with a glenoid socket cup or the glenoid socket itself. These parts of the anatomy differ significantly from the situs of the thumb. The shoulder is the most mobile joint in the body and is naturally an enarthrodial (ball and socket) type joint. The basal thumb, however, does not have naturally the mobility of the

shoulder, and, in nature, is not a ball and socket type joint but rather is a saddle joint. It is only in artificial prosthetic implantation that the basal thumb joint is converted, as it were, to a ball and socket type connection. The long bone of the upper humerus is shaped differently, both internally and externally, from that of the metacarpus, into which the differing stems go.

Furthermore, I question why it is that a person of ordinary skill has not reduced the size of either a hip or a shoulder implant to develop a good basal thumb implant. And as I see it, for example, with respect to the Swanson Basal Thumb Implant, a person of ordinary skill did not "look to other prior art prostheses for designing the structure of the implant."

With respect to a finger digit implant such as that of Bekki et al., my initial impression when I was informed that finger digit joint art was being applied to a basal thumb joint was that of being confounded. These joints are not related sufficiently to be interchangeable. Several considerations come to mind in support of this: configuration, materials and implant situs.

The configuration of a finger digit joint implant differs fundamentally from that of a basal thumb joint implant. First, a typical finger digit joint implant as represented by Bekki et al. has a discontinuous head with respect to sphericity whereas the basal thumb joint under consideration has a head with an articulating surface that is uninterrupted as to its sphericity. This is so that the peculiarities of the finger joint such as a lesser degree of mobility or tendon interference are taken into account. The stem, too, of the Bekki et al. implant does not resemble that of the basal thumb joint implant of the present invention, in particular in its preferred embodiments, which can be readily seen.

The materials of the Bekki et al. joint, even as a composite structure, do not resemble those of the present basal thumb joint having a modular ceramic head. The Bekki et al. joint is said to be preferably either of ceramic or can have a metal-based, ceramic-coated head, with the implant component itself still of one piece. In contrast, the modular basal thumb joint implant of the present invention which has a ceramic head is a two-part component, and prefers a monolithic ceramic head part attachable to a monolithic metal stem part. Moreover, quick bone ingrowth is not relevant to the head of the modular ceramic-headed basal thumb joint implant of the invention. Such a consideration would be counterproductive to functionality of the thumb joint and harmful to the patient.

As to the implant situs, as alluded to above, a finger digit joint is significantly different from a basal thumb joint, both in natural and in artificial implant environments. The finger joint, for one thing, is significantly constrained whereas the basal thumb joint has far more degrees of freedom of movement,

Townley, 10/758455 Decl. w/Exhibits (Exhibits)

Townley, 09/352472 Pringle DECLARATION, p. 11

which is essential for a properly functioning joint.

It appears, therefore, that the application of the references noted above to the claims of the present invention is untenable.

All statements made herein of my own knowledge are true. All statements made herein on information and belief are believed to be true.

Dated: March 9, 2001

Patrick E. Pringle

Attachments

Townley, 10/758455 Decl. w/Exhibits (Exhibits)

Recd
Amendment with Formal Drawings (9pp.) 1gcjr 5/14/2000
(+) 3 sheets drwgs.
Record of Interview 1gcjr & AJR
DECLARATION OF MARK S. LESLIE, M.D. 1gMSL
#390.00 (ck. #896)
Re: Townley
09/352472
BASAL THUMB JOINT IMPLANT.
Christopher John Rudy
PTO #31873 5/16/2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the patent application of

Charles O. Townley
Serial No. 09/352,472
Filing Date 07/14/99
For BASAL THUMB JOINT IMPLANT

To the attention of

Group Art Unit 3738
Examiner Brian E. Pellegrino

Commissioner of Patents
Washington, D.C. 20231

DECLARATION OF MARK S. LESLIE, M.D.

I, Mark S. Leslie, hereby state and declare that:

I am a citizen of the United States of America and resident of Traverse City, Michigan. Further, I am a licensed physician and orthopaedic surgeon practicing in Traverse City. I graduated with the M.D. degree in 1980 A.D., and have been certified by the American Board of Orthopaedic Surgeons since 1988. I specialize in surgery to the hand. Attached hereto is my Curriculum Vitae.

I understand that the claims of the present application have been rejected under Section 102(b), Title 35, United States Code, allegedly for a public use or sale of the invention prior to July 14, 1998. The Examiner stated in setting forth his rejection:

> Claims 1-20 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. In May of 1998, Charles O. Townley sold the implant to Dr. Leslie. A product can be sold if its confidentiality is agreed/-implied upon. However, no such agreement for the confidentiality of the implant was agreed upon in the statement/explanation of the sale. The purchaser, Dr. Leslie, of the product/invention which was sold by the inventor/-company was asked, "Let me know how this works." However, BIOPRO/Dr. Townley did not receive any feedback from the buyer, so it was assumed that the thumb implant worked fine. Further purchases by the original buyer, Dr. Leslie, reinforced the fact that it was working well. This is not experimental use of the invention, since no agreement to keep it confidential was stated and no reports were required. Proper experimentation requires positive and/or negative feedback.

I also understand that prior to the rejection, Dr. Townley's attorney, Christopher John Rudy, had reported to the Examiner the following information, as he understood it, pertinent thereto:

I wish to note the following:

Although Mr. Rudy's report to the Patent Office as set forth on the previous page would seem to be accurate and reasonable in general, in correction of some of Mr. Rudy's understandings of the invention as would pertain to me as reported on the previous page, as I recall, with respect to his stating that the head was too large, only the head at the large end of the spectrum appeared to be a bit too large; the head at the small end of the spectrum seemed to be a bit too small. However, the intermediate sizes of the heads did not seem to present significant problems in my estimation. Also, as I recall now, I thought that the tri-flanges and curved stem and so forth could be acceptable, but, being part of a new and different thumb joint implant, should necessitate a trial. In addition, I did not purchase the basal thumb joints of the present invention which I implanted; these were actually purchased by Munson Medical Center Hospital, at which I have staff privileges.

Attached hereto are FIGS. 1-13 of the invention from the present application of Dr. Townley. I received, on a first user basis from BioPro, Inc., non-modular thumb joint implants such as depicted in FIGS. 1-3 and 12. The stems had cross-sections like those depicted in FIGS. 5 and 6. FIG. 12 most accurately depicts how the thumb joint implants I received looked, and FIG. 13 shows in general how the implant looks when implanted. I understand that the basal thumb joint implants which I received were made of a cobalt alloy. I did not receive any modular joint implants such as depicted in FIGS. 4 and 7-9, nor do I recall any porous coating on the implants I received such as depicted in FIGS. 10 and 11.

I did consider my use of the basal thumb joint implants experimental, especially for the first year, since they were clearly different from the otherwise broadly analogous Swanson titanium basal thumb joint known then, and thus, again, their configuration should require a clinical trial to determine if the new basal thumb joint implants could be adequately employed in general. Before the critical date of July 14, 1998, I received and implanted in a patient one non-modular basal thumb joint of the present invention as referenced above.

Although no formal written agreement of confidentiality was entered into between me and BioPro, Inc., I understood that the basal thumb joint implant invention, which was paid for by Munson Medical Center, was to be tried in confidence, and any such disclosure of the invention was on a need to know basis. Thus, I informed my patients in whom the joints were to be implanted that I would be implanting an experimental joint, and, of course, so as to attain informed consent, these patients viewed the joint. However, I made no public disclosure of the invention, nor did I promote it among my colleagues. Thus, the invention was kept in appropriate confidence, especially during the critical period.

Also, although I understand that, based on the foregoing report from Mr. Rudy, he did not report to the Patent Office nor do I recall being expressly asked, "Let me know how this works," in contrast to that which the patent Examiner stated in setting forth his rejection, I understood that I was to keep track of results, but that reporting of results could be anecdotal. Thus, my reporting of results could be, and was done, informally. In general, I found that the joint performed fairly well, and I conveyed this at least on an informal basis to BioPro, Inc.

Accordingly, as I understand it, there was no public use by me nor non-experimentally-based sale of the present thumb joint invention before the critical date under 35 U.S.C. 102(b).

All statements made herein of my own knowledge are true, and all statements made herein on information and belief are believed to be true. Furthermore, these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under 18 USC 1001, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Mark S. Leslie

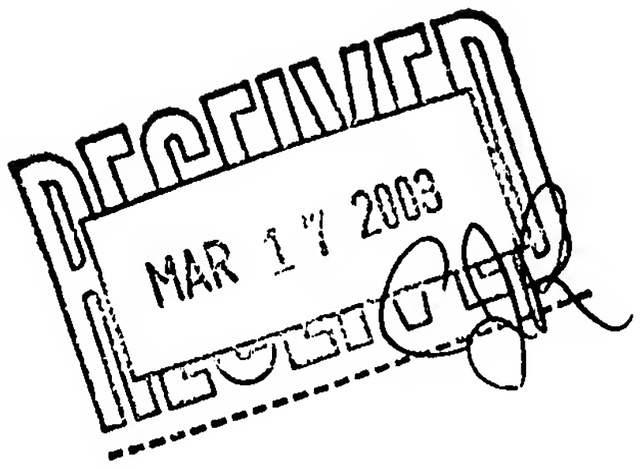
5/10/05
Date

Attmts: Attmt A (C.V.)
Attmt B (FIGS. 1-13)

Paper No. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES



Ex parte CHARLES O. TOWNLEY

Appeal No. 2003-0155
Application No. 09/352,472

ON BRIEF

MAILED

MAR 13 2003

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Before ABRAMS, FRANKFORT, and McQUADE, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-7, 21, 22, 24 and 25. Claims 18-20 have been allowed, claims 12-17 canceled, and claims 8-11, 23 and 26 withdrawn from consideration as being directed to a non-elected invention.

We AFFIRM-IN-PART.

BACKGROUND

The appellant's invention relates to a basal thumb joint implant. An understanding of the invention can be derived from a reading of exemplary claim 1, which has been reproduced below.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Whipple et al. (Whipple)	5,702,469	Dec. 30, 1997
Klawitter et al. (Klawitter)	5,782,927	Jul. 21, 1998

Claims 1 and 3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Whipple.

Claims 1-7, 21, 22, 24 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Klawitter.

Claims 21 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Whipple.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the Answer (Paper No. 30) and the final rejection (Paper No. 25) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 29) and Reply Brief (Paper No. 32) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

Claim 1

> A basal thumb joint implant comprising a head including a single, smooth, generally hemispherical, medio-proximally directed, articulating surface, and a generally abrupt, distally directed truncation thereto, said generally hemispherical articulating surface being continuous as to its sphericity and uninterrupted up to said truncation so that said generally hemispherical articulating surface defines a truncated ball; and a stem attached to the head, which arises from the truncation of the head and includes at least one of the following features:
>
> A) a general angle of attachment to the head which is acute in relation to the truncation of the head;
>
> B) a flanged cross-sectional stem profile;
>
> C) an inwardly curved stem;
>
> D) an eccentric head attachment site for the stem;
>
> wherein said implant has its head of a size for mounting in and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and its stem of a size for intramedullary insertion in metacarpal bone stock.

The Rejection Under Section 102

Anticipation is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention. See In re Paulsen, 30 F.3d 1475, 1480-1481, 31 USPQ2d 1671, 1675 (Fed. Cir. 1994) and In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). Anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or recognition of inherent properties that may be possessed by the reference. See Verdegaal Brothers Inc. v. Union Oil Co. of California, 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987). Nor does it require that the reference teach what the applicant is claiming, but only that the claim on appeal "read on" something disclosed in the reference, *i.e.*, all limitations of the claim are found in the reference. See Kalman v. Kimberly-Clark Corp, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984).

Claims 1 and 3 stand rejected as being anticipated by Whipple. It is the examiner's view that Whipple discloses in Figure 3B a thumb joint prosthesis having a flanged stem profile and a head of generally hemispherical shape that is uninterrupted up to its truncation (Paper No. 25, page 3). The appellant argues in opposition that Whipple does not anticipate the subject matter of these claims because (1) it does not disclose a flanged cross-sectional profile, (2) the head is made to mate with a second

manufactured component rather than bone, and (3) the head is not generally hemispherical in shape (Brief, pages 4 and 5; Reply Brief, pages 3 and 4). We are not persuaded by any of these arguments that the rejection should not stand, and therefore we shall sustain it. Our reasoning follows.

Claim 1 requires that the stem have a flanged cross-sectional profile. The common applicable definition of "flange" is a "rib or rim for strength, for guiding, or for attachment to another object,"[1] As the examiner has pointed out, the projections and notches shown in Figure 3B of Whipple constitute "flanges" when the stem is viewed in an appropriate cross-section. Additionally, although unnumbered, a flange clearly is present in Whipple's Figure 3B at the base of the stem, spaced slightly from the truncation of the head, and a cross-section taken through this portion of the stem would be "flanged." Thus, this feature of claim 1 is disclosed by Whipple.

The fact that the Whipple thumb joint implant element shown in Figure 3B is described in conjunction with mounting in a corresponding second implant element rather than directly into bone does not disqualify it as an anticipatory element. As we pointed about above in relating the guidance provided by our reviewing court for evaluating rejections under Section 102, anticipation requires only that the claim read on something disclosed in the reference, and such is the case here.

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[1]See, for example, Webster's New Collegiate Dictionary, 1973, page 436.

As pictured in the appellant's drawings, the head of the implant is in the shape of a hemisphere, that is, one-half of a sphere. As recited in claim 1, however, and as explained in the specification, the invention comprises a head having "a single, smooth, generally hemispherical" articulating surface with "a generally abrupt, distally directed truncation thereto." The presence of the amplifying term "generally"[2] causes claim 1 not to be limited only to an exact hemispherical shape. The question then becomes what constitutes a "generally" hemispherical surface as opposed to a surface that is not "generally" hemispherical, and this question is not precisely answered in the specification. It is, however, clear from the language used in claim 1 that a complete hemisphere is not required, a conclusion that is confirmed by the further recitation in the claim that the "generally hemispherical" surface terminates in "a generally abrupt . . . truncation thereto." To "truncate" is to shorten by or as if cutting off,[3] and thus a truncation of a hemisphere is less than a hemisphere.

We therefore agree with the examiner that in Figure 3B Whipple discloses an implant head that is "generally hemispherical . . . continuous . . . and uninterrupted up to said truncation," as is stated in claim 1. This understanding is further supported by Whipple's own description of the metacarpal component (122) as being of "a generally

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[2]The common definition for "generally" is "in disregard of specific instances with regard to an overall picture." Webster's New Collegiate Dictionary, 1973, page 478.

[3]Webster's New Collegiate Dictionary, 1973, page 1255.

truncated hemispherical shape" (col 2, lines 17-29). Since Whipple thus discloses all of the subject matter recited in claim 1, the claim is anticipated, and we will sustain the Section 102 rejection thereof. The like rejection of claim 3 is sustained inasmuch as the appellant has elected to group in with claim 1 (Brief, page 3).

The Rejections Under Section 103

The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. See, for example, In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In establishing a prima facie case of obviousness, it is incumbent upon the examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

Claims 1-7, 21, 22, 24 and 25 stand rejected as being unpatentable over Klawitter, which is directed to a joint replacement for a human finger. With reference particularly to Figures 3A and 5, the examiner is of the view that all of the subject matter recited in claim 1 is disclosed by Klawitter, except that the head has cuts (52) removed

to allow passage of the ligaments and therefore does not teach a head surface that is "continuous as to its sphericity and uninterrupted up to said truncation," as is required by independent claims 1, 21 and 24. However, it is the examiner's position (Paper No. 25, page 4) that

> [i]t would have been obvious to one of ordinary skill in the art not to remove material from the joint head that forms a relief cut in the metacarpel element of Klawitter in order to use for a joint that does not obstruct the path of the ligaments. The manufacturing of an "uninterrupted" head is a step backward in the art.

We do not agree.

Even if Klawitter is considered, arguendo, to be analogous art (the appellant argues that it is not because it is directed to finger joints), we fail to perceive any teaching, suggestion or incentive which would have led one of ordinary skill in the art to manufacture the Klawitter joint implant without the cuts necessary to allow passage of the ligaments of the finger, for to do so would render the device unsuitable for its intended purpose. Continuing on the same theme, there is no evidence from which to conclude that one of ordinary skill in the art would have found it obvious to utilize the Klawitter joint implant on the thumb, in view of the different considerations necessary for a thumb joint, which are attested to on page 10 of the Pringle declaration.

It therefore is our conclusion that Klawitter does not establish a prima facie case of obviousness with regard to the subject matter recited in independent claims 1, 21

and 24 or, it follows, of dependent claims 2-7, 22 and 25, and we will not sustain this rejection.

Claims 21 and 22 are rejected as being unpatentable over Whipple. The appellant has urged at the outset that Whipple constitutes nonanalogous art in that it is directed to a two-piece joint implant rather than the one-piece implant to which claims 21 and 22 are directed. We find this argument not to be persuasive. It is our opinion that Whipple would have commended itself to an inventor's attention in considering the problems of thumb joints because it also deals with the replacement of joints in the hand. See In re Clay, 966 F.2d 656, 659, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992). While the appellant has argued that this would not be the case, no evidence has been presented in support thereof, and argument and conclusionary statements of the applicant do not constitute objective evidence of nonobviousness. See In re deBlauwe, 736 F.2d 699, 222 USPQ 191 (Fed. Cir. 1984). Also in this regard, it is interesting to note that claim 21 does not contain the "wherein" clause of the last four lines of claim 1, which states that the head is sized for mounting in a concavely prepared surface of trapezium bone stock, and this would seem to undermine the appellant's assertion in the nonanalogous art argument that the claim is directed to a device to be implanted only in bone.

We have discussed Whipple above in the context of the Section 102 rejection of claim 1. Claim 21 differs from claim 1 in that it further requires the head to have a diameter of 13mm to 19mm. However, while Whipple is silent as to the dimensions of the thumb implant disclosed therein, it is our view that it would have been obvious to one of ordinary skill in the art to provide a thumb joint implant with appropriate dimensions for implantation in a particular human being, such as the claimed range, for in an obviousness assessment skill is presumed on the part of the artisan, rather than the lack thereof. In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

We therefore conclude that Whipple establishes a prima facie case of obviousness with regard to the subject matter recited in claim 21, and we will sustain the rejection of claim 21 and of claim 22, the separate patentability of which was not argued.

CONCLUSION

The rejection of claims 1 and 3 as being anticipated by Whipple is sustained.

The rejection of claims 1-7, 21, 22, 24 and 25 as being unpatentable over Klawitter is not sustained.

The rejection of claims 21 and 22 as being unpatentable over Whipple is sustained.

A rejection of claims 1, 3, 21 and 22 having been sustained, the decision of the examiner is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

NEAL E. ABRAMS)
Administrative Patent Judge)
)
)
)
CHARLES E. FRANKFORT) BOARD OF PATENT
Administrative Patent Judge) APPEALS
) AND
) INTERFERENCES
)
)
)
JOHN P. McQUADE)
Administrative Patent Judge)

NEA:pgg

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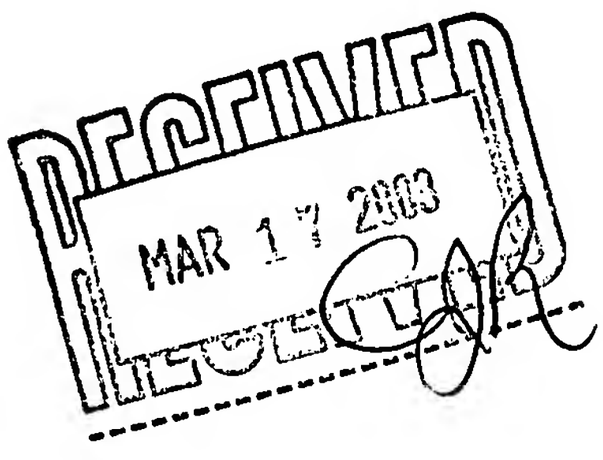
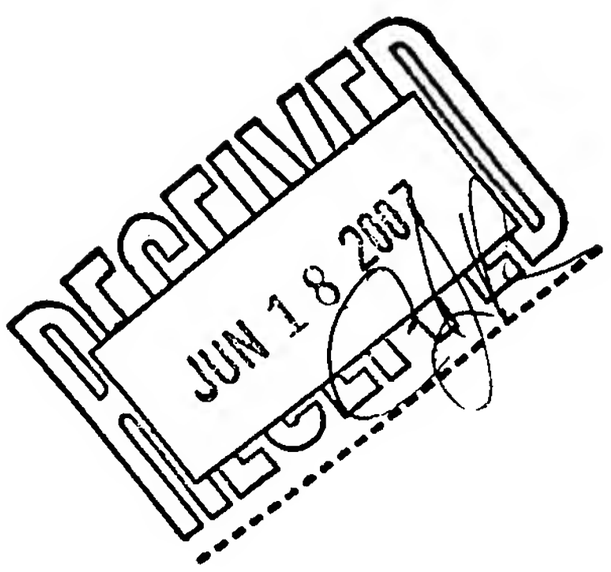


The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHARLES O. TOWNLEY



Appeal 2007-0570
Application 09/352,472
Technology Center 3700

Decided: June 14, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and LORA M. GREEN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 31-54, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a basal thumb joint implant. Claim 31 is illustrative:

31. A basal thumb joint implant comprising a head including a single, smooth, generally hemispherical, medio-proximally directed, articulating surface, and a generally abrupt, distally directed, planar end to the head, which defines an end to said articulating surface, said articulating surface being continuous as to its sphericity and uninterrupted up to the end of said articulating surface so that said articulating surface defines a truncated ball of a shape that is from substantially hemispherical to greater than substantially hemispherical; and a stem attached to and projecting from the head along an axis, which arises from the generally planar end to the head and includes at least one of the following features:

(A) a general angle of projection from the head, which is acute in relation to the generally planar end to the head so as to help align the stem in intramedullary bone stock that has been resected substantially normal to its proximal end;

(B) a flanged cross-sectional stem profile, which , when taken in cross-section perpendicularly to the stem, is in a tri-flange shape, with three flanges without notches extending distally on the stem, which helps provide for a precise fit with metacarpal medullary canal anatomy, hence preserving bone stock and assuring optimal long term stability, including near if not complete immovability with respect to rotation, of the implant;

(C) an inwardly curved stem so as to help avoid a propensity for dislocation of a replaced joint, and which helps provide for a precise

fit with metacarpal medullary canal anatomy, hence preserving bone stock and assuring optimal long term stability, including near if not complete immovability with respect to rotation, of the implant; and

(D) an eccentric head attachment site for the stem so as to help avoid a propensity for dislocation of a replaced joint;

wherein said implant has its head of a size for mounting in and articulating with a correspondingly concavely prepared surface of trapezium bone stock; its stem of a size for intramedullary insertion in metacarpal bone stock; and such feature(s) of an anatomically oriented arrangement help(s) permit an unobstructed range of normal pain free motion.

The Examiner relies on the following prior art references to show unpatentability:

Smith	US 3,314,420	Apr. 18, 1967
Bekki	US 5,007,932	Apr. 16, 1991

Wright Technology brochure of the Swanson implant submitted on 9/1/99.

The rejections as presented by the Examiner are as follows:

1. Claims 31-40, 42-44, 47, 48, 50-52, and 54 stand rejected under 35 U.S.C. § 102(b) based upon an admitted public use or sale of the invention.

2. Claims 45, 46, 49, and 53 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the public use of the invention in view of Smith or Bekki.

3. Claims 31, 36, and 41 stand rejected under 35 U.S.C § 103(a) as unpatentable over Wright and Smith.

We reverse.

DISCUSSION

Public Use and Sale:

Claims 31-40, 42-44, 47, 48, 50-52, and 54 stand rejected under 35 U.S.C. § 102(b) based upon an admitted public use or sale of the invention. In addition, claims 45, 46, 49, and 53 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the public use of the invention in view of Smith or Bekki. The Examiner relies on Smith and Bekki to teach prosthetic devices made from a ceramic material (Answer 4-5). According to the Examiner, the use of ceramic materials provides joint implant devices with a lighter weight and better bone ingrowth properties. However, neither Smith nor Bekki teach the structural requirements of Appellant's claimed implant.

To reach the structural requirements of Appellant's claimed implant, the Examiner relies on Appellant's admission that the implant was sold more than one year prior to the filing date of the application (Answer 3). Appellant does not dispute that the claimed implant was sold prior to the filing date of the instant invention. To the contrary, Appellant specifically discloses that the device was sold and used more than one year prior to the filing date (Information Disclosure Statement (IDS)[1] 2-3). Appellant asserts, however, that the sale and use of the device prior to the filing date of the application falls within the scope of the experimental use exception (Br. 4-12).

Therefore, we find that the decisive issue before us is whether the sale and use of Appellant's claimed implant more than one year prior to the filing

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[1] Received September 1, 1999.

date of the application falls within the experimental use exception. In our opinion, the weight of the evidence falls in favor of Appellant.

> [T]he question posed by the experimental use doctrine, assessed under the first prong of the two-part on-sale bar test of *Pfaff* [*v. Wells Elecs.*, 525 U.S. 55, 67-68, 48 USPQ 1646, 1647 (1998)], is not whether the invention was under development, subject to testing, or otherwise still in its experimental stage at the time of the asserted sale. Instead, the question is whether the transaction constituting the sale was not incidental to the primary purpose of experimentation, *i.e.*, whether the primary purpose of the inventor at the time of the sale, as determined from an objective evaluation of the facts surrounding the transaction, was to conduct experimentation.

Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co., 417 F.3d 1203, 1210, 75 USPQ2d 1650, 1654 (Fed. Cir. 2005). Accordingly, it is necessary to look "to objective evidence to show that a pre-critical date sale was primarily for experimentation." *Id.* at 1212, 75 USPQ2d at 1656. Our appellate reviewing court has catalogued and consolidated a list of factors that are representative of the "various kinds of evidence relevant to the question of whether pre-critical date activities involving the patented invention-either public use or sale were primarily experimental and not commercial." *Id.* at 1213, 75 USPQ2d at 1657, citing *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353, 63 USPQ2d 1769, 1779 (Fed. Cir. 2002). Appellant has specifically addressed these factors and supported his assertions with the Declarations of Leslie, Townley, and Pringle[2] (Br. 5-12).

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[2] Executed February 9, 2004, the second Pringle declaration.

In sum, the evidence of record establishes, *inter alia*, that:

1. The basal thumb joint implant was offered to Mark S. Leslie, M.D., an orthopedic hand surgeon, as a first user, prior to the critical date. "Dr. Leslie was informed as a condition of his use that the basal thumb joint implant was experimental, and he acknowledged this prior to conveyance of the implant" (Townley Declaration 4). Dr. Leslie also understood that the device was to be tried in confidence (Leslie Declaration 3).

2. The inventor retained control over the experimental use of the device (Leslie Declaration 2 ("performance of the implant was to be closely monitored and reported to BioPro. Inc."); Townley Declaration 4 ("Dr Leslie "was informed and he understood that he was to closely monitor and keep track of results")).

3. Despite the experimental use of the implant, it was customary in this industry to sell the device in order to recoup some of the development costs of the implant (Br. 8; Townley Declaration 4).

4. The doctor using the implant, Dr. Leslie, considered his use of the implant experimental because it was "clearly different from the otherwise broadly analogous Swanson Titanium basal thumb joint known than, and thus, . . . their configuration should require a clinical trial to determine if the new basal thumb joint implants could be adequately employed in general" (Leslie Declaration 3. *See also* Pringle Declaration 4 ("it would be appropriate to desire to field test a device that has passed a simple FDA record review for a certain level of safety and effectiveness to see if its improvements engender a higher level of effectiveness in vivo than required by FDA and to see if further modifications would be in order. That is what was done with . . . Dr. Leslie. . .")).

5. "[T]he length of the test period was only that necessary to evaluate the device under field conditions. It was only about a year overall, with the sole pre-critical date sale occurring in the first two months of that. The present application was filed promptly after a satisfactory technical evaluation period ended" (Br. 8; IDS 3; Townley Declaration 5 ("Based upon the reports from Dr. Leslie, and my own work, I became satisfied that the implant was successfully performing technically in the filed, and . . . the present application was diligently prepared and filed.")).

6. There was no commercial exploitation of the device prior to the critical period (Townley Declaration 4).

In our opinion, this evidence strongly suggests that the sale and use of the claimed device prior to the critical date was for experimental purposes, and therefore the sale and use of the claimed device prior to the critical date falls within the experimental use exception.

For his part, the Examiner finds that experimental use has not been established because Appellant received payment for the device, which was FDA approved. In addition, the Examiner finds that Appellant failed to favor this record with documented evidence of a confidentiality agreement, any modification to the device as a result of the experimental use, or the records maintained during the experimental use. The Examiner does not, however, make any attempt to address the declaratory evidence or weigh this evidence in the context of the factors set forth in *Allen Eng'g Corp*. At best, the Examiner has simply stated his unsupported opinion that the evidence of record is insufficient to establish that the use of the device prior to the critical date was for experimental purposes. Accordingly, when viewed as a whole, we find that the weight of the evidence falls in favor of Appellant.

The sale and use of the device prior to the critical date was for experimental purposes and falls within the experimental use exception.

Accordingly, we reverse the rejection of claims 31-40, 42-44, 47, 48, 50-52, and 54 under 35 U.S.C. § 102(b) based upon an admitted public use or sale of the invention.

Having found that the use and sale of the device prior to the critical date falls within the experimental use exception, the combination of Appellant's admitted public use and sale of the invention with Smith or Bekki must also fall because neither secondary reference teaches Appellant's claimed implant. Accordingly, we reverse the rejection of claims 45, 46, 49, and 53 under 35 U.S.C. § 103(a) as unpatentable over the public use of the invention in view of Smith or Bekki.

Wright and Smith:

Claims 31, 36, and 41 stand rejected under 35 U.S.C § 103(a) as unpatentable over Wright and Smith. Claim 31 is drawn to a basal thumb joint implant. The implant includes, *inter alia*, at least one of the following features: (A) an acute projection angle, (B) a flanged cross-sectional stem profile, (C) an inwardly curved stem, and (D) an eccentric head attachment. Claim 36 depends from and further limits claim 31 to require that the implant has at least the eccentric head attachment site for the stem.

The Examiner finds that Wright teaches a basal thumb joint implant having a head that is "'eccentrically attached to the stem' since it appears

off-centered and is not a complete ball head" (Answer 4). In contrast, Appellant asserts that

> [t]he head of the Wright . . . implant does not appear to be eccentrically attached to the stem. It is not off-centered. See, the reproduced photo on the first (cover) page of the Wright brochure; the drawing on the bottom portion of the brochure's third page; and the X-ray on the top right hand side of the brochure's fourth page.

(Reply Br. 1.) In response, the Examiner does nothing more than reassert that Wright teaches an eccentric attachment site (Answer 6). Upon review of Wright, we find that the weight of the evidence falls in favor of Appellant. Wright's photo, schematic and X-rays (Wright cover page and 2-5) fail to illustrate an implant which has an eccentric head attachment site for the stem so as to help avoid a propensity for dislocation of a replaced joint as required by claims 31 and 36. In addition, the Examiner fails to direct our attention to any portion of Wright, and we find none, to suggest that the implant has an eccentric head attachment site for the stem. Accordingly, we find that Wright fails to support the Examiner's prima facie case of obviousness.

Claim 41 depends from and further limits claim 31 to require that the implant is made of a suitable ceramic material. Recognizing that Wright does not teach the use of a ceramic for the implant, the Examiner relies on Smith to teach a prosthesis formed from a ceramic material (Answer 4). Smith does not, however, make up for Wright's failure to teach an eccentric head attachment site for the stem.

For the foregoing reasons, we reverse the rejection of claims 31, 36, and 41 under 35 U.S.C § 103(a) as unpatentable over Wright and Smith.

CONCLUSION

In summary, we reverse all rejections of record.

REVERSED

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